Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
664677		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2004/011333	06.08.2004	08.08.2003

International Patent Classification (IPC) or national classification and IPC

A61K31/4545, 9/14, 47/10, 47/26, 47/36, 47/38, A61P37/08

Applicant

SCHERING CORPORATION

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2004/011333

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* _____ received by this Authority on _____

nos.* _____ received by this Authority on _____

☐ the drawings:

sheets _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2004/011333

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-18	YES
	Claims		NO
Inventive step (IS)	Claims	5	YES
	Claims	1-4, 6-18	NO
Industrial applicability (IA)	Claims	1-18	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Documents cited in the international search report:

Document 1: JP 57-035586 A, entire text

Document 2: JP 9-208495 A, claims 1 and 7; paragraphs [0010] and [0011]

Document 3: Dai Jusan Kai Nippon Yakkyokukata Kaisetsusho, 1996, Kabushiki Kaisha Hirokawa Shoten, A107, lines 24 to 30

Document 4: JP 6-157312 A, paragraphs [0002], [0006] and [0009]

Document 5: JP 11-029463 A, claims 1, 4 and 5, paragraph [0001]

Newly cited document:

Document 6: WO 2001/76607 A1 (Nichiiko Pharmaceutical Co., Ltd.), 18 October 2001, entire text

Claims 1 to 4 and 8 to 18

The invention set forth in claims 1 to 4 and 8 to 18 does not involve an inventive step in the light of documents 1 to 5.

Dry syrup is a dosage form which would be well known to a person skilled in the art, therefore it would be easy for a person skilled in the art to conceive of

attempting to obtain a dry syrup preparation for loratadine, which is a known drug, as set forth in document 1.

In addition, as indicated in documents 2 to 4, hydroxypropyl cellulose, other cellulose derivatives and saccharides such as sucrose are known as additives to dry syrup, therefore the use of these additives when obtaining a dry syrup for loratadine is a matter which a person skilled in the art could accomplish as necessary.

Moreover, document 5 indicates that by using hydroxypropyl cellulose it is possible to obtain an aqueous suspended solution with good redispersibility for a substance with poor solubility. It would therefore be easy for a person skilled in the art to predict the effect disclosed in this application, i.e. good dispersibility.

Claim 5

The invention set forth in claim 5 is novel and involves an inventive step.

According to the embodiment disclosed in the response to the written opinion submitted by the applicant, it is understood that when hydroxypropyl cellulose HPC-SSL which satisfies the requirements set forth in claim 5 is used, better dispersibility and antifoaming properties are obtained than for hydroxypropyl cellulose HPC-SL, whose viscosity falls outside the prescribed range. Moreover, none of the documents cited in the international search report or the newly cited document discloses or suggests this feature.

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Claims 6 and 7

The invention set forth in claims 6 and 7 does not involve an inventive step in the light of documents 1 to 4.

As set forth in documents 2 and 4, an alginate is known as an additive to dry syrup, therefore using these additives when obtaining a dry syrup containing loratadine is a matter which a person skilled in the art could accomplish as necessary.

In addition, in reference to the description of this application, there is not even one embodiment which does not contain hydroxypropyl cellulose but contains only an alginate, therefore it is impossible to acknowledge that such an embodiment has a special effect in terms of dispersibility.

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1 and 8-16

Claim 1 relates to a dry syrup comprising as an active ingredient a compound defined by the desired property of "binder that upon addition of water at use, provides a uniform dispersion". It appears from the description, paragraph [0012], that the "binder that upon addition of water at use, provides a uniform dispersion" refers to all of such binder compounds that any dry syrup having the same added thereto satisfies the requirements (i) to (v) recited in claim 12.

However, only examples wherein hydroxypropyl cellulose was added are disclosed in the description of this application. Thus, it appears that only some of the claimed compounds are disclosed within the meaning of PCT Article 5, so that the support by disclosure in the description within the meaning of PCT Article 6 is lacking.

Further, with respect to the "binder that upon addition of water at use, provides a uniform dispersion", as apparent from the above, whether or not compounds are the relevant binder compounds cannot be judged unless the final compositions are obtained. The scope of compounds with this property cannot be specified even if technical common knowledge at the time of filing of this application is taken into account. Therefore, claim 1 also fails to satisfy the requirement of clarity prescribed in PCT Article 6.

The same applies to claims 8-16.